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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,604	12/07/2001	Pablo D. Garcia	002441.00008	6543

7590 06/27/2005

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EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/016,604	Applicant(s) GARCIA ET AL.	
	Examiner Ulrike Winkler	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9,10 and 13-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,10 and 13-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

5.2.0

DETAILED ACTION

The Amendment filed August 4, 2004 in response to the Office Action of March 10, 2004 is acknowledged and has been entered. Claims 8, 12 and 16-38 have been cancelled. Claims 1-7, 9-11, 13-15 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Objections

The objection of claim 11 is **withdrawn** in view of applicants' cancellation of the claim.

Claim Rejections - 35 USC § 112

The rejection of claims 1-3, 9-11 and 13-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **maintained** for reasons of record. In an attempt to clarify what is included with the term HML-2 applicants have amended the claims to read "human endogenous MMTV-like subgroup 2 (HML-2)." The new claim language does not help identify the structure required for the purpose of diagnosis.

Applicants argument is that one of ordinary skill would know what sequences would fall with the HML-2 subgroup and which ones do not. This argument does not address the problem with identifying which structures are critical for the claimed method. Therefore, applicants have not distinctly claimed the subject matter that is encompassed by the invention.

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The rejection of claims 1-3, 9-11 and 13-15 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is maintained** for reasons of record. Applicant's arguments have been fully considered but fail to persuade. Applicants' arguments are that HML-2 sequences are known in the art and that the ordinary artisan would know which structure belong in the HML-2 subgroup and which ones do not, citing Zsiros et al.

In response the art indicates that HML-2 comprises a diverse group of retroelements (Zsiros et al. Journal of General Virology, 1998, listed on IDS; see figures) having diverse structures at the nucleic acid level. The art has not correlated the occurrence with an increased HML-2 to any disease stage. HERV-K (HML-2) is expressed in normal tissue as well as cancerous tissue (see table 2, Stauffer et al. Digital expression profiles of human endogenous retroviral families in normal and cancerous tissues. Cancer Immunity (2004) Vol. 4, pp. 1-18). Because the expression can occur in both cancerous and normal tissue an increase in expression will not correlate with a diagnosis of any kind of disease. A diagnosis could only be made with those sequences for which such a correlation has been established and would be limited to specific sequences. The HERV-K (HML-2) family is expressed in normal muscle tissue and is overexpressed in normal brain, skin and pancreas as well as in cancers of the brain, head and neck, uterus. The level of expression of HERV-K 22q11 is higher in normal prostate tissue than in prostate cancers (see table 2, Stauffer et al., 2004, page 12, 2nd paragraph). Therefore, only the isolated polynucleotide sequences that have actually been correlated with prostate cancer meet the written description provision of 35 U.S.C. §112, first paragraph.

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The rejection of claims 1-7, 9-11 and 13-15 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is **maintained** for reasons of record. Applicant's amendment does not help to identify the particular virus contemplated for the detection of prostate cancer. Applicants argue that the term diagnosis includes a screening assay that may require further analysis. Applicants assert that the office has not provided any evidence to doubt that HML-2 variants will not predictably associate with prostate cancer.

In response the art indicates that HML-2 comprises a diverse group of retroelements (Zsiros et al. Journal of General Virology, 1998, listed on IDS; see figures) having diverse structures at the nucleic acid level. The art has not correlated the occurrence with an increased HML-2 to any disease stage. HERV-K (HML-2) is expressed in normal tissue as well as cancerous tissue (see table 2, Stauffer et al. Digital expression profiles of human endogenous retroviral families in normal and cancerous tissues. Cancer Immunity (2004) Vol. 4, pp. 1-18). Because the expression can occur in both cancerous and normal tissue an increase in expression will not correlate with a diagnosis of any kind of disease. A diagnosis could only be made with those sequences for which such a correlation has been established and would be limited to specific sequences. The HERV-K (HML-2) family is expressed in normal muscle tissue and is overexpressed in normal brain, skin and pancreas as well as in cancers of the brain, head and neck, uterus. The level of expression of HERV-K 22q11 is higher in normal prostate tissue than in prostate cancers (see table 2, Stauffer et al., 2004, page 12, 2nd paragraph). Because on observation in the increase level of an endogenous retrovirus does not necessarily correlate with

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a particular cancer the instant invention is rejected as not being enabled for the full scope claimed

Conclusion

No claims allowed.

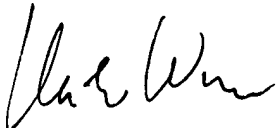
Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.


ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER

6/23/05